European Alliance for Personalised Medicine

ESMO Roundtable Agenda

EAPM seeks innovation solutions at ESMO

18 September 2020
08.00 – 16.00

VIRTUALLY

Introduction

For the 8th year in succession, EAPM will be present at the prestigious ESMO Congress and will, for the fifth time, be hosting a satellite meeting as part of the events. In the same way as our own recent events, the focus will be on bringing innovation into healthcare systems, but with very specific items on the Alliance agenda, which will be on the issue of biomarkers and molecular diagnostics

EAPM's roundtable is currently scheduled to take place on 18 September (at the premier oncology gathering in Madrid, Spain.) This is, of course, dependent upon the situation at the time with respect to the Covid-19 pandemic situation.

Hopefully, by mid-September, life will at least be beginning to get back to something approaching normal. One thing is absolutely certain, the situation caused by the novel coronavirus, it's effect on EU healthcare systems, and the fall-out going forward, will be among the hottest topics.

Event and format

The roundtables will commence at 08.00 and finish at 16.00, and will feature three two-hour sessions. These are currently scheduled as follows:

08.00 – 10.00 Session 1: Tumor Agnostics

Tumour-agnostics aim to target patients based on a highly specific rare driver mutation (which could be present in less than 1 percent of solid tumours) rather than on the actual type of tumour. Put another way, tissue-agnostic cancer drugs are anti-neoplastic medicines that treat cancers based on the mutations that they display, instead of the tissue type in which they appear. These drugs include, for example, Entrectinib, Pembrolizumab and Larotrectinib.

As with many drugs, the current system of value assessment diagnostic infrastructure are not fully adequate. This obviously affects patient access in a negative way.

Also, the health issues involved only affect smaller patient populations and there is, as ever, a deficit when it comes to clinical trial data. Meanwhile, high-quality diagnostic tests are urgently required.

As ever, full stakeholder alignment and interaction is key going forward. This has so far proven difficult as, despite the emergence of personalised therapies, disparities continue to exist among stakeholder groups around the recognition of tumor-agnostic therapies and their role in cancer.

Given the rare incidence of these cancers, meanwhile, patients are very often not up-to-speed either, being relatively low on awareness and, thus, influence.

Obvious needs stand out, not least that for a coordinated approach to registry development and better use of NGS technology - although the latter has become common in cancer research.

Certainly required is commitment from policymakers and payers to ensure adequate reimbursement and funding, while building capacity. This will greatly benefit patients, as well as bring about savings across our healthcare systems.

Key Questions to be addressed will be as follows:

- Is tumour agnostic a paradigm shift in cancer treatment?
- What are the key challenges for tumor-agnostic patient so as to ensure access and reimbursement?
- Are there key recommendations for policymakers, regulators, payers and industry so as to ensure tumor-agnostic treatments can be successfully integrated into clinical practice?

08.00 – 08.10 **Setting the framework**

Denis Horgan, *Executive Director, EAPM*

08.10 – 08.35 **Prioritisation and government Support**

Allan Hackshaw, *Deputy Director, Cancer Research UK & UCL Cancer Trials Centre, University College London*
Rosa Giuliani, *Consultant in Medical Oncology at The Clatterbridge Cancer*

Discussion

Q&A

08.35 – 09.15 **HTA acceptance of Tumor and novel data sources**

Fabrice Barlesi, *Medical Director of Gustave Roussy*
Lotte Steuten, *Vice President & Head of Consulting, Office of Health Economics*

Discussion

Q&A

09.15– 09.45 **Policy Priorities**

Giuseppe Curigliano, *Associate Professor of Medical Oncology, University of Milano; Head of the Division of Early Drug Development, European Institute of Oncology*
Sushil Patel, *Franchise Head Lung, Agnostic, Skin & Rare Cancers VP, Global Product Strategy, Oncology, F. Hoffmann-La Roche AG*

09.45– 09.55 **Policy Discussion**

Discussion with All Speakers

09.55 – 10.00 **Conclusion**

Denis Horgan, *Executive Director, EAPM*
Rosa Giuliani, *Consultant in Medical Oncology at The Clatterbridge Cancer Center*

10.30 – 13.00 Session II: Biomarkers and Molecular Diagnostics

A lot has been said about testing, and often the lack of it, in terms of **the Covid-19 outbreak, with different countries adopting different strategies** and, also, having different resources when it comes to getting necessary kits. While that topic will certainly arise in this session, the key focus here will be on better and more equitable access to biomarkers and molecular diagnostics across Europe. This is a must, but we're a long way short of it.

Access to personalised medicine and new diagnostic technologies can help resolve many inefficiencies, such as trial-and-error dosing, the potential for increased hospitalisation time due to adverse drug reactions and the problem of late diagnoses. It may also enhance the effectiveness of therapies through better tailored treatment administration.

However, all of this raises concerns and questions from payers. An important cause of limited access to, and the use of, molecular diagnostics across Europe is a lack of clear reimbursement pathways.

It is estimated that diagnostics account for less than 2% of total healthcare spending, but influence 60% of clinical decision making. The assessment of the value of these tests remains to be clarified in most healthcare systems. The current approach does not reward value creation, nor does it incentivise evidence generation to support value demonstration.
As a consequence, most European patients are effectively denied access. This cannot be allowed to continue into the third decade of the 21st century.

Lest we forget, biomarker testing lies at the heart of personalised medicine. And molecular diagnostics offer important benefits to patients, because they can provide patients with the use of safer and more effective therapies, as well as increased confidence about treatment decisions.

But in order to allow patients to fully benefit from biomarkers and molecular diagnostics, some key concerns need to be addressed, such as the need for patients access to these new technologies. With the goal of developing a framework for optimal and minimal testing, the following elements will be discussed in four sections, which come under their own main topics.

First up is access and reimbursement, which will entail reviewing data to address long-term cost-benefit ratios and redefining healthcare budgets and processes. Meanwhile, when it comes to assessing access to quality biomarker testing, we need to urgently review timelines and procedures to access, define testing standards, and take a long, hard look at the role and education of stakeholders - with a view to ensuring appropriate information at the right time.

Also up for discussion during this meeting will be assessing and addressing obstacles to the integration of access to diagnostic/biomarkers into Europe's healthcare systems, and identifying best practices and their added value.

The ultimate aim is to reach consensus on a framework to improve biomarker access in oncology.

Question to be addressed:

- What do you think needs to be done for quicker adoption of new biomarkers into clinical practice?

- What is the biggest challenge you and your team face in the adoption of molecular diagnostics in your institution/country?
- Is biomarker testing regularly implemented as part of national guidelines in the management of certain cancers? For example, are Her2/neu and ER/PR *always* examined in breast cancer?
- What is the Optimal and Minimum Framework?

10.30 – 10.40 **Setting the framework**

Denis Horgan, *Executive Director, EAPM*
Dolors Montserrat*, Member of the European Parliament*

10.40 – 11.45 **Minimum Resources to achieve best standard of care for Biomarker Testing**

Reinhard Buettner, *Director of Department of Pathology,University Hospital Cologne, Köln*
Pierfranco Conte, *Full Professor of Oncology and Director of the Post Doctoral Fellowship Programme in Medical Oncology at the University of Padova*
Ash Sharma*, Head of Strategic Marketing and Market Access, Global Oncology Diagnostics, AstraZeneca*
Rodrigo Dienstmann, *Principal Investigator of the Oncology Data Science Group of the Vall d'Hebron Institute of Oncology (VHIO)*

Discussion

Q&A

11.45 – 12.30 **Optimal Resources to achieve best standard of care for Biomarker testing**

Frederique Penault-Llorca*, Director, Centre de Lutte Contre le Cancer de Clermont-Ferrand*
Keith Kerr*, Consultant Pathologist, Department of Pathology, Aberdeen University*
Benjamin Gannon, *Vice President International Access, Policy And Advocacy, Myriad genetics*

Discussion

Q&A

12.30 – 12.55 **Policy Discussion**

All Speakers

12.55 – 13.00 **Conclusion and Next Steps**

Denis Horgan, *Executive Director, EAPM*

13.30 – 15.30 Session III: Utilising Real-World Evidence in a healthcare setting

Scene Setter

After many successful high-level roundtables held in recent times, EAPM now takes the road to Madrid and ESMO to to seek the best ways forward for the implementation of Real-World Evidence (RWE) into healthcare in Europe.

During the course of the meeting at the premier cancer gathering, EAPM, alongside its members and stakeholders, will look to find consensus with key decision makers, including at Member State level, not least with representatives in the European Parliament, on how to proceed in this area.

RWE for healthcare is a simple concept - harnessing various health data in real time to help make faster and better medical decisions.

What is Real World Evidence?

Real-World Evidence is an umbrella term for different types of healthcare data that are not collected in conventional randomised controlled trials, including patient data, data from clinicians, hospital data, data from payers and social data.

RWE is crucial to the implementation of adaptive clinical trials. Medical Adaptive Pathways to Patients (MAPPs) are currently being tested in a European Medicine Agency pilot project, which calls MAPPs "a prospectively planned process, starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorisation to expand access to the medicine to broader patient populations."

It is the 'iterative phases of evidence gathering' that ideally will utilise RWE to more accurately detect patient responses to new therapies in real time.

Focus Areas of the Roundtable:

This roundtable will specifically focus on the barriers in existence today, and offer a multi-stakeholder path to adoption by the key representatives of healthcare in the EU's Member States.

What are current barriers to the Implementation of Real World Evidence?

- The required data infrastructures do not exist everywhere in Europe
- The data collection systems are not harmonised and many of the most successful implementations are customised locally
- The technology evolves quicker than regulation can adapt
- Regulatory authorities at the member state level are not currently equipped to base decisions on real-world evidence
- The current "Right to Be Forgotten" data protection legislation may compromise the ability to use Real World Evidence in clinical development
- Next generation healthcare harnessing Real World Evidence will be increasingly *multisectoral* and multidisciplinary, challenging the current status-quo of regulatory oversight

What are the regulatory needs for the implementation of Real World Evidence?

- Regulators should facilitate health information technology implementations that are driven by current best practices with the understanding that all processes will need the ability to adapt rapidly to evolving technologies

- EU regulators should support projects that investigate the use of real world data for approval and reimbursement of new therapies at the member state level
- The opinions of patients with conditions for which there are currently limited treatment options must be incorporated when considering alternative evidence bases such as real world data
- The current data protection legislation should be reconsidered with regards to healthcare, as it may place Europe at an international disadvantage for the use of real world datq
- The EU should allow for a wide scope of eHealth and mHealth applications without over-regulating the sector, similar to the 'light touch' approach of the FDA with regards to mHealth

13.30 – 13.40 **Setting the framework**

Denis Horgan, *Executive Director, EAPM*

13.40 – 14.10 **Oncology needs for the implementation of Real-World Evidence**

Benedikt Westphalen, *Koordinator Molekulare Onkologie, Comprehensive Cancer Centre, University of Munich*
Christophe Le Tourneau, *senior Medical Oncologist at the Institut Curie and Full Professor of Medicine at Paris-Saclay University*

Discussion

Q&A

14.10 – 14.40 **Policy Frameworks for the implementation of Real-World Evidence**

Inaki Gutierrez Ibarluzea, *Director of Organisational and Managerial Innovation of the Basque Foundation for Health Innovation and Research*
Lars G. Hemkens, *Deputy Director of the Basel Institute for Clinical Epidemiology and Biostatistics (ceb) and Senior Scientist, Department of Clincial Research, University Hospital Basel*

Discussion

Q&A

14.40 – 15.10 **Multi-stakeholders Needs for implementation of Real-World Evidence**

Stefan Gijssels, *Executive Director, Digestive Cancers Europe*
Frederik Buijs, *Global Medical Director, Real World Evidence, Roche*

Discussion

Q&A

15.10 – 15.25 **Discussion: Policy Priorities**

Ralf Herold, *Scientific Officer, Oncology, Haematology & Diagnostics, Scientific & Regulatory Management Department, European Medicines Agency (EMA)*
Beata Jagielska, *Head of the Oncological diagnostics, Cardiological Oncology and Palliative Medicine Clinic, National Institute of Oncology Maria Skłodowska-Curie*

Discussion

Q&A

15.25 – 15.30 **Conclusion**

Denis Horgan, *Executive Director, EAPM*

15.30 – 16.00 Conference: Closing Session

Denis Horgan, *Executive Director, EAPM*
Ken Matris, *Board Member, European Cancer Patient Coalition*
Rosa Giuliani, *Consultant in Medical Oncology at The Clatterbridge Cancer Center*
Fabrizia Galli, *Vice-President, ABRCAdaBRA*